

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR
SYSTEMS INC. and ABBOTT
LABORATORIES INC.,

Plaintiffs,

v.

MEDTRONIC VASCULAR, INC. and
MEDTRONIC USA, INC.,

Defendants.

)
)
) C. A. No. 98-80 (SLR)
) (Consolidated with C.A. No. 98-314
) (SLR) and C.A. No. 98-316 (SLR))
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**ACS'S OPENING BRIEF IN SUPPORT OF ITS
MOTION FOR PERMANENT INJUNCTION**

Frederick L. Cottrell, III (#2555)
cottrell@rlf.com

Anne Shea Gaza (#4093)
gaza@rlf.com

RICHARDS, LAYTON & FINGER
One Rodney Square
P.O. Box 551
Wilmington, DE 19899
(302) 651-7509

*Attorneys for Plaintiffs Abbott Cardiovascular
Systems Inc. and Abbott Laboratories Inc.*

OF COUNSEL:

J. Michael Jakes

Gerald F. Ivey

Michael A. Morin

FINNEGAN, HENDERSON, FARABOW

GARRETT & DUNNER, L.L.P.

901 New York Avenue, N.W.

Washington, D.C. 20001-4413

(202) 408-4000

(202) 408-4400

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I. INTRODUCTION

Plaintiffs Abbott Cardiovascular Systems Inc. and Abbott Laboratories Inc. (collectively “ACS”)¹ submit this brief in support of their motion for a permanent injunction to enjoin Medtronic Vascular, Inc. and Medtronic USA, Inc. (collectively “Medtronic”) from infringing the claims of U.S. Patents Nos. 5,514,154, 6,066,167, 6,066,168, and 6,432,133 (collectively “the Lau patents”).

II. NATURE AND STAGE OF PROCEEDINGS

After a trial from February 7-18, 2005, a jury rendered a verdict that all of Medtronic’s accused stents infringed ACS’s Lau patents, and that the Lau patents are not invalid. (D.I. 629.) On June 7-8, 2005, the Court held a bench trial to hear Medtronic’s inequitable conduct defense. (D.I. 670-71.) On March 30, 2007, the Court denied Medtronic’s motions for judgment as a matter of law and a new trial. (D.I. 711.) On April 24, 2007, the Court ruled that the Lau patents were not unenforceable. (D.I. 713.) On May 2, 2007, the Court entered judgment on the liability issues in ACS’s favor, which it amended on May 21, 2007. (D.I. 715, 719.)

On May 9, 2007, Medtronic filed a notice of appeal. ACS moved to dismiss the appeal as premature because the Court has yet to address ACS’s request for an injunction.

III. SUMMARY OF ARGUMENT

The Federal Circuit admonished that “[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected.” *Windsurfing Int’l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n.12

¹ Guidant sold its vascular intervention business (including its stent business) to Abbott on April 21, 2006, while post-trial motions were pending. Accordingly, on June 26, 2007, Plaintiffs filed an unopposed motion to rename the plaintiffs in this case Abbott Cardiovascular Systems Inc. (Advanced Cardiovascular Systems, Inc.’s new name) and Abbott Laboratories Inc. (Guidant Sales Corporation’s successor in the stent business). (D.I. 723.)

(Fed. Cir. 1986). Yet that is exactly what Medtronic did. For nearly ten years, Medtronic competed in the stent market by infringing ACS's patent rights. Throughout those years, Medtronic released infringing stent after infringing stent without regard for ACS's patents, and has shown no sign of stopping. The decade of infringement proved extremely lucrative for Medtronic too, selling billions of dollars worth of infringing stents and cementing a significant share of the U.S. bare-metal stent market. Medtronic's decade of infringement significantly harmed ACS as well—and not just in terms of lost sales. Aside from lost profits, ACS also lost market share, goodwill, and opportunity.

Under these circumstances, all four *eBay* factors favor an injunction.

First, ACS suffered irreparable harm from Medtronic's infringement, and will continue to do so unless and until Medtronic's unauthorized activities cease. ACS and Medtronic are head-to-head competitors in the stent market, so there is no question that Medtronic's infringement directly damaged ACS's market share and goodwill, which are primary considerations in courts' decisions to grant injunctions, especially after *eBay*. And Medtronic's infringement damaged ACS in other ways as well.

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Second, ACS's legal remedies are inadequate. The primary value of a patent rests in the statutory right to exclude others from infringing. There is no adequate legal remedy for ACS's loss of market share, the corrosion of its goodwill, or the resources it lost (and will continue to lose) as a result of Medtronic's infringement.

Third, the balance of hardships favors ACS. Whereas ACS invented the patented technology and brought it to fruition, Medtronic built its entire stent business by infringing ACS's patents. After a decade of infringement, ACS should be able to enjoy the remaining years of its right to exclude others before the patents expire. Moreover, given that Medtronic's U.S. stent sales now comprise only a miniscule fraction of Medtronic's overall revenue, an injunction will not work an insurmountable hardship on Medtronic. But even were the case otherwise, any such hardship would not be *unfair* as it was a direct and foreseeable consequence of Medtronic's decision to infringe.

Finally, the public interest favors an injunction. The public is best served by a robust patent system, where companies respect their competitors' patents. Moreover, there is no evidence that physicians or patients will be adversely affected by an injunction on Medtronic's infringing stents. And Medtronic can hardly complain that such an injunction would be improper or against the public interest, given that it is currently seeking injunctions against all three of its major competitors—ACS, Cordis, and Boston Scientific—on both bare-metal stents and drug eluting stents (DES).

In short, the equities favor an injunction, so that Medtronic's decade of infringement will come to an end.

IV. STATEMENT OF FACTS

A. ACS's Connected-Ring Stent Takes the U.S. Stent Market by Storm

Before ACS released its patented stent design, the U.S. coronary stent market essentially consisted of two types of stents: coil designs (the Gianturco-Roubin and Wiktor stents) and a slotted-tube design (the Palmaz-Schatz stent). (D.I. 631 at 217-231, 274-275.) Each of these "first-generation" designs, however, had significant flaws. The coil designs were highly flexible and could be delivered through tortuous vessels, such as the coronary arteries, but lacked

sufficient radial strength and thus were incapable of adequately supporting a vessel lumen once deployed. (*Id.*) On the other end of the spectrum, the slotted-tube design offered good radial strength, but lacked longitudinal flexibility and thus could not be used to treat highly tortuous vessels. (*Id.*)

Faced with these problems, ACS developed a novel, connected-ring design that provides a stent with an ideal combination of radial strength and longitudinal flexibility. (D.I. 631 at 245-53; D.I. 637 at 1592-93.) This “second-generation” design, embodied in ACS’s Multi-Link family of stents, revolutionized the stent market by permitting physicians to stent previously untreatable vessels. (*Id.*)

From the moment of its U.S. release in October 1997, ACS’s Multi-Link stent was a stunning commercial success. In just a few short months, ACS’s stent gained approximately 64% of the U.S. market. (Ex. 4² at ACS00687025; Ex. 6, Pacitti Decl. at ¶ 3.) During that same time period, the prior market leader, Cordis’s Palmaz-Schatz stent, plummeted from a 67% market share to approximately 23%. (*Id.*; Ex. 6, Pacitti Decl. at ¶¶ 2-3.) By any measure, ACS’s revolutionary stent design was an unprecedented success. Indeed, in an article in the Wall Street Journal in 1998, one analyst described the shift of market share from Johnson & Johnson to ACS as “the most dramatic transfer of wealth between two companies in medical-device history.” (Ex. 1 at A1.)

B. Medtronic Releases Infringing Products That Take ACS’s Market Share and Damage the Goodwill of ACS’s Stent Business

While ACS was developing its patented connected-ring design, Medtronic (then AVE) developed a completely different type of stent based on a rudimentary design concept by Michael

² References to “Ex. ___” refer to the exhibits attached to the affidavit of Anne Shea Gaza filed herewith.

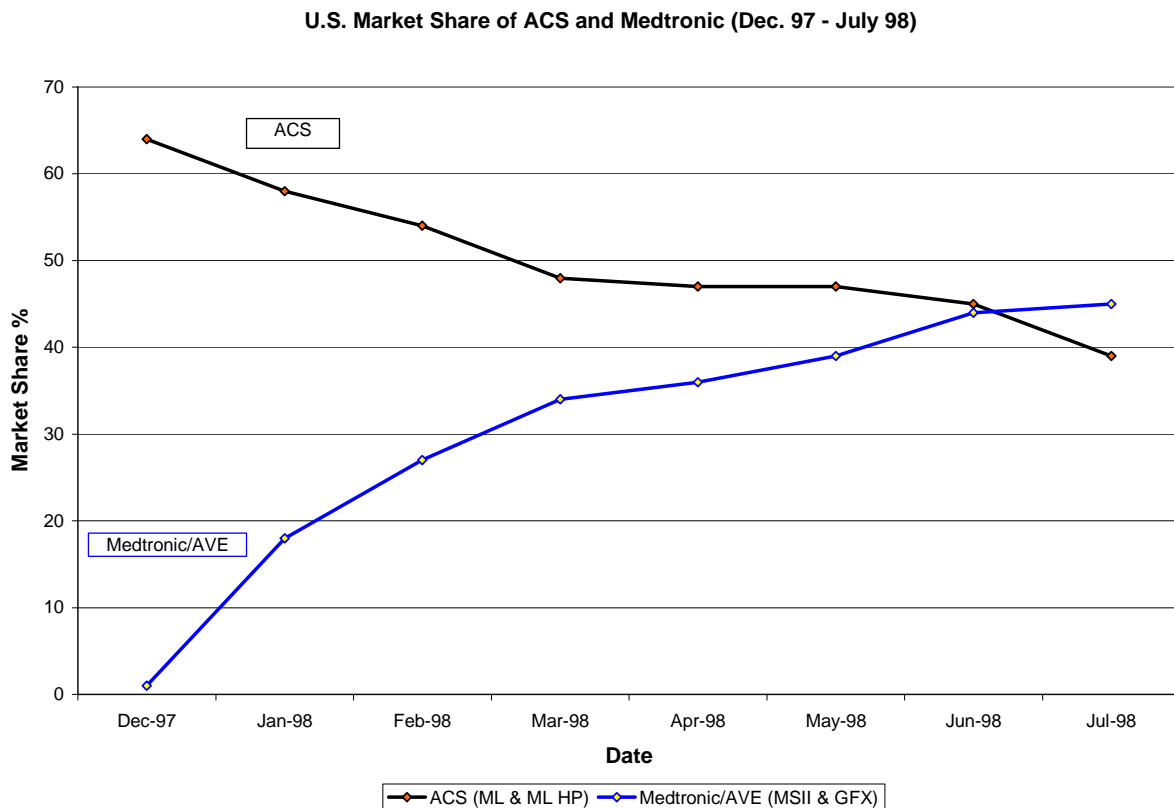
Boneau. (D.I. 637 at 1587-1591; Ex. 3 at AVEA019806-07.) Medtronic's version of Mr. Boneau's design, called the MicroStent PL, consisted of one or more 4 mm long Boneau stents mounted, unconnected, on a balloon. (*Id.*) The Boneau design, however, was unsuccessful, and the MicroStent PL was never released in the United States. (*Id.*)

Following its failed attempt to develop the Boneau design into a workable stent, Medtronic went "back to the drawing board" in an attempt to modify that design in hopes of creating a successful, second-generation stent. (Ex. 2 at 200:18-24.) Its next attempt, the MicroStent I, consisted of two 4-mm stents welded together to form an 8-mm stent, which was then mounted on the same balloon with another 8-mm stent to cover 16-mm lesion lengths. (Ex. 3 at AVEA019807.) Like the MicroStent PL, however, the MicroStent I proved to be a failure, and was never released in the U.S. market.

After these repeated failures, Medtronic resorted to appropriating ACS's connected-ring technology. In December 1997, only months after ACS's launch of its Multi-Link stent, Medtronic released its first infringing stent in the United States, the MicroStent II. (Ex. 4 at ACS00687025; Ex. 6, Pacitti Decl. at ¶ 4.) Unlike Medtronic's prior designs, the MicroStent II was successful, and directly captured market share from ACS. Indeed, within a few months of its release, Medtronic captured one-third of the U.S. market. (Ex. 5 at ACS00687356; Ex. 6, Pacitti Decl. at ¶ 4.) During that same time period, ACS's market share dropped 16 percentage points, from 64% to 48%. (*Id.*)

In December 1997, the month that Medtronic released its infringing MicroStent II, ACS brought suit in the Northern District of California to stop Medtronic's infringement, requesting, *inter alia*, an injunction to stop Medtronic from infringing ACS's Lau patents and monetary damages. That suit was transferred here, and consolidated into this case.

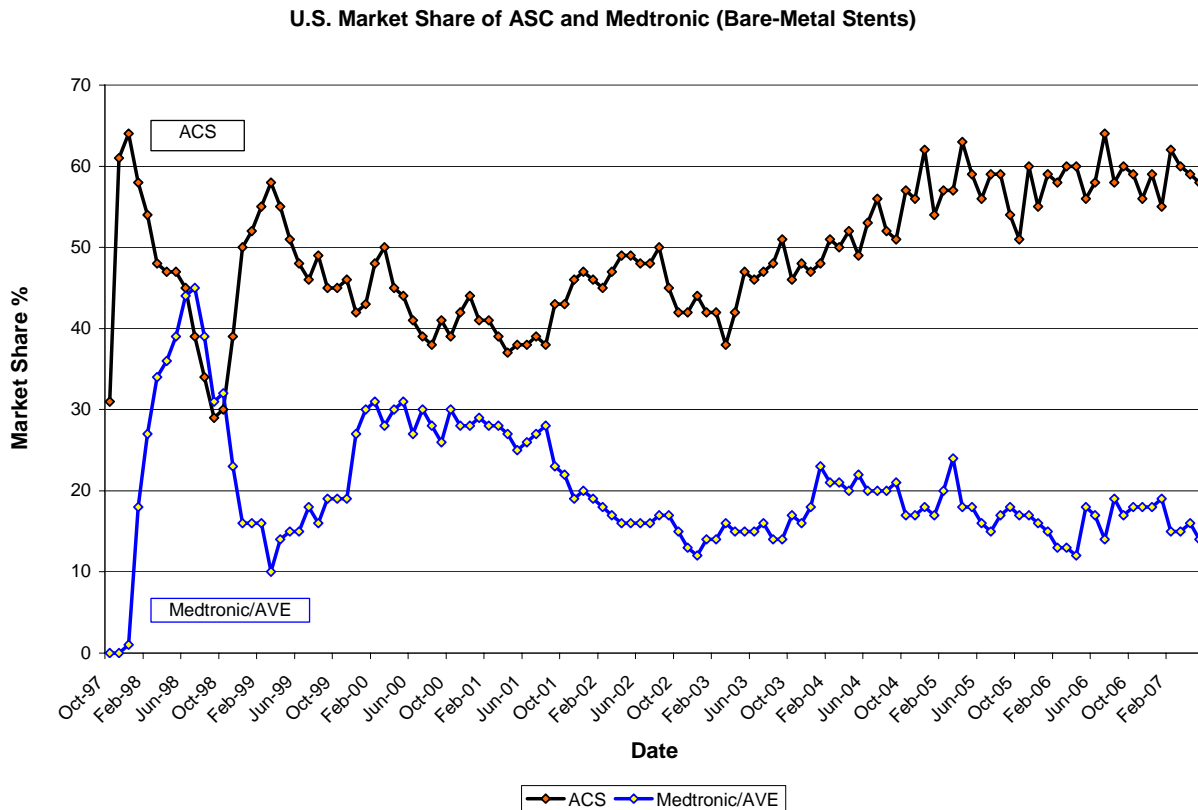
Undeterred by the lawsuit, however, in April 1998, Medtronic released yet another infringing stent—the GFX, which took even more market share from ACS. (*Id.*; Ex. 6, Pacitti Decl. at ¶ 5.) By July 1998, due to Medtronic’s combined marketing of the MicroStent II and the GFX, ACS’s market share tumbled still further, to 39%, while Medtronic’s skyrocketed to 45%. (*Id.*) The following chart illustrates how Medtronic’s infringing products took substantial market share from ACS in just a few short months after their release. (Ex. 6, Pacitti Decl. at ¶ 6.)



As illustrated on this chart, riding on the back of ACS’s patented technology, by July 1998, Medtronic captured the leadership position in the market from ACS for the first time since the release of ACS’s Multi-Link in the fall of 1997.

While ACS quickly reclaimed its lead in the stent market with the release of its next Multi-Link stent (the “Duet”) in November 1998, and held onto that position in the bare-metal

stent market ever since, Medtronic continued to hold a substantial share of the market by releasing additional infringing products. To ACS's direct detriment, almost every new infringing stent yielded an increase in Medtronic's market share and, simultaneously, a loss in ACS's market share. The significant relationship between Medtronic's market share and ACS's market share becomes readily apparent when the relative market shares are plotted against one another.



Significantly, with the exception of a handful of noninfringing “Wiktor” stents, Medtronic’s stent business over the past decade consists entirely of infringing stents. Medtronic’s infringement was neither accidental nor unintended. Indeed, in the ten years since this suit was filed, Medtronic has released additional stents, each of which the jury found to infringe ACS’s Lau patents—i.e., the GFX, the GFX 2, the GFX 2.5, the BeStent2, the S540, the S660, the S670, the S7, the Driver, the MicroDriver, and the Racer—at a rate of more than one

per year. Medtronic apparently made no effort during the past decade to introduce a noninfringing stent, such as a new version of the “Wiktor” coil stent.

Medtronic’s infringement caused incalculable damage to ACS’s vascular intervention business. While ACS obviously suffered substantial lost profits on sales of stents that ACS would have made but for Medtronic’s infringement, ACS’s damages extend far beyond that.

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³ References to “Pacitti Decl.” refer to the Declaration of David C. Pacitti, attached as Ex. 6.

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Additionally, ACS's loss of market share damaged the goodwill of ACS's business in the eyes of investors. (Ex. 6, Pacitti Decl. at ¶ 10.) When valuing a medical device company such as ACS, investors place substantial emphasis on the company's share in the market. (*Id.*; Ex. 21.) By usurping ACS's market share, Medtronic diminished the goodwill—and thus value—of ACS's business to current and potential investors. (*Id.*)

C. The Court Rules That Medtronic Infringed ACS's Patents

In February 2005, a jury found that all of Medtronic's accused stents infringe the asserted claims of ACS's patents, and that none of the asserted claims is invalid. (D.I. 629.) Yet, in the two and a half years that followed, Medtronic has not stopped infringing. Even now that the Court denied Medtronic's post-trial motions (D.I. 712), upheld the enforceability of the patents (D.I. 713), and entered judgment in ACS's favor (D.I. 715, 719), Medtronic continues to infringe, advertising its infringing Driver and Micro-Driver products for sale on its web page. *See* http://www.medtronic.com/physician/vascular/cs_home.html. Medtronic shows no signs of stopping either. Absent an injunction, Medtronic's infringement will continue and, in fact, multiply, as explained below.

D. ACS Settles Patent Litigation with Cordis and Boston Scientific Involving Their Connected-Ring Stents and Competing Patent Claims

ACS has *never* licensed its Lau patents to a third party for money alone. Rather, the few licenses ACS granted were purely in the context of settlements and cross-licenses. (Ex. 8,

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Schneiderman Decl. at ¶ 5.) Specifically, after Medtronic began infringing ACS's Lau patents, other competitors, including Cordis and Boston Scientific, followed suit. As it did here, ACS initiated litigation against both parties, suing Cordis in the Northern District of California and Boston Scientific in the Southern District of Indiana. (*Id.* at ¶¶ 2-3.) At that time, Cordis and Boston Scientific also had asserted patent claims against ACS's Multi-Link stents, requesting injunctive relief and monetary damages. All of these disputes, however, were ultimately resolved by settlements and cross-license agreements that ended multiple lawsuits both by and against ACS. (*Id.*⁵) As part of these settlements, ACS licensed its Lau patents to Cordis and Boston Scientific, but *only* in exchange for licenses on their competing patents. (*Id.*; Ex. 10; Ex. 11; Ex. 12.)

ACS has a general policy against licensing its Lau patents simply for money and has no interest in licensing them to Medtronic or anyone else on that basis. (*Id.* at ¶ 6.) It should not be forced to do so now, against its will.

E. Medtronic's Plans to Multiply Its Infringement by Releasing an Infringing Driver Stent with a Drug Coating

1. Drug-Eluting Stents Change the Landscape of the Stent Market

In 2003, the U.S. stent market was dramatically changed by the launch of DES products. The first such product was Cordis's "Cypher" stent, which includes a stent coated with a drug that is designed to be released when the stent is implanted in a vessel. (Ex. 13.) The Cypher stent is on the market under a license to ACS's Lau patents. In 2004, Boston Scientific released the second competing DES product ("Taxus"). (Ex. 14.) As with the Cypher, the Taxus is also on the market under a license to ACS's Lau patents.

⁵ References to "Schneiderman Decl." refer to the Declaration of Gary Schneiderman, Ph.D, attached as Ex. 8.

While ACS and Medtronic have both maintained a sizeable share of the bare-metal (i.e., non-DES) stent market, demand for such stents declined precipitously after Cordis's and Boston Scientific's DES products hit the U.S. stent market. (Ex. 15.) For example, in 2006, ACS had only 5.1% of the overall stent market (including DES) and Medtronic had only 1.3%. (Ex. 21 at 5) As a result, while Medtronic's past sales of its infringing stents were much larger, during its fiscal year for 2006, Medtronic reported U.S. sales of bare-metal stents totaling only \$24 million, which was merely 0.21% of Medtronic's overall total sales. (Ex. 17 at 26.)

2. Medtronic's Intent to Release a Drug-Coated Driver Stent

To compete with Cordis and Boston Scientific in the DES-dominated U.S. stent market, both ACS and Medtronic have been developing DES products. While each company recently launched its product outside of the U.S., neither has done so within the U.S. (Ex. 6, Pacitti Decl at ¶ 11.)

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Medtronic's DES, called the "Endeavor," is simply an infringing Driver stent coated with a drug. (Ex. 18 ("The Medtronic Endeavor Drug Eluting Coronary Stent system combines Medtronic's Driver Coronary Stent, the drug ABT-578 and a PC polymer into a drug eluting stent system designed to reduce restenosis.")) While Medtronic could have developed its DES on a stent platform that did not infringe ACS's Lau patents, such as its Wiktor design, Medtronic

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instead chose to use an infringing stent, despite being on notice of its infringement for nearly a decade. Indeed, notwithstanding the jury verdict in 2005 and the Court's recent judgment of infringement, Medtronic has shown no signs of altering its stated intentions of releasing a drug-coated version of its infringing Driver stent and thereby multiplying its infringement substantially.

In 2006, the DES segment of the U.S. stent market was approximately \$2.9 billion per year. (Ex. 21 at 5.) Currently, the DES segment of the U.S. stent market is split between Cordis's Cypher stent and Boston Scientific's Taxus stent. (*Id.*; Ex. 15.) Despite their positive claims to reducing restenosis, however, the Cypher and Taxus stents have suffered some negative press due to the occurrence of late-stent thrombosis. (Ex. 6, Pacitti Decl. at ¶ 12.) As a result, the next entrant into the DES segment of the U.S. stent market will have an even better opportunity to take market share away from both Cordis and Boston Scientific and develop long-standing relationships with customers. (*Id.*) Thus, the stakes are high in the race between Medtronic and ACS to release the next DES product.

F. Medtronic's Stents Are Not Necessary for the U.S. Stent Market

If Medtronic is enjoined from selling its infringing stents, ACS has ample capacity to supply all of Medtronic's current customers with bare-metal stents that could be used in place of the infringing stents. Indeed, in 2002, prior to the emergence of the DES market in the United States, ACS alone produced more than 890,000 stents (Ex. 20), whereas in 2006 it sold only approximately 187,000 stents, and Medtronic sold around 49,400 (Ex. 21 at 5). Thus, ACS has ample capacity to satisfy demand.

In addition to sufficient capacity, ACS and its licensees provide a sufficient selection of sizes and varieties of stents necessary for U.S. physicians to perform all desired procedures, even

if Medtronic's stents are enjoined. (Ex. 16, Kahn Decl. at ¶ 7.⁷) As explained by Dr. Joel Kahn, Medtronic's stents are no safer or more effective than other stents on the market, such as those made by ACS, Boston Scientific, and Cordis. (*Id.*) Based on the variety of competing stents currently available, neither physicians nor patients will be harmed if Medtronic's infringing stents are taken off the market. (*Id.*)

From a physician's standpoint, moreover, Medtronic's Endeavor stent, which is merely a drug-coated Driver, provides no significant additional medical benefit to the public. (Ex. 16, Kahn Decl. at ¶¶ 10-15.) Indeed, studies show that the Endeavor may even result in more restenosis than Cordis's Cypher.⁸ (*Id.*) While Medtronic attempts to capitalize on the recent bad press for the Cypher and Taxus stents, touting its Endeavor as having no reported cases of late-stent thrombosis, the data on late-stent thrombosis for the Endeavor is inconclusive. (*Id.* at ¶ 14.) Accordingly, Medtronic's Endeavor appears to be no better (and potentially worse for restenosis) than the DES products currently on the market.

V. THE COURT SHOULD ISSUE A PERMANENT INJUNCTION

Pursuant to 35 U.S.C. § 283, the Court "may grant injunctions in accordance with the principles of equity to prevent a violation of any right secured by a patent, on such terms as the court deems reasonable." *Id.* In *eBay, Inc. v. MercExchange, L.L.C.*, 126 S.Ct. 1837 (2006), the Supreme Court emphasized that the traditional four-factor test must be applied to determine whether a permanent injunction should issue:

⁷ References to "Kahn Decl." refer to the Declaration of Joel K. Kahn, M.D., attached as Ex. 16.

⁸ One study showed that Endeavor had a lower rate of myocardial infarction than Cypher; however, due to the small sample size of the study, these results were deemed inconclusive. (Ex. 16, Kahn Decl. at ¶ 12.)

According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

Id. at 1839. The Supreme Court further held that “the decision whether to grant or deny injunctive relief rests within the ‘equitable discretion of’ the district courts, and that such discretion must be exercised consistent with principles of equity.” *Id.* at 1841. Under the present circumstances, the Court should issue an injunction.

A. ACS Has Suffered Irreparable Harm

1. Medtronic’s Infringement Is Causing Irreparable Harm

The facts show that Medtronic’s infringement is causing irreparable harm. ACS is a market leader in medical devices, seeking to exert its right to exclude one of its primary competitors from using its intellectual property. As explained by this Court in *Novozymes A/S v. Genencor Int’l, Inc.*, 474 F. Supp. 2d 592 (D. Del. 2007), ACS has a right not to assist its direct competitors, such as Medtronic, by permitting them to use ACS’s patented technology. *Id.* at 613 (granting injunction after *eBay* and emphasizing that “[t]hese are head-to-head competitors, and Novozymes has a right, granted by Congress, not to assist its rival with the use of proprietary technology.”).

After *eBay*, moreover, a patentee may show irreparable harm where a head-to-head competitor, such as Medtronic, is infringing on the patentee’s right to exclude others from practicing its patent. *Novozymes*, 474 F. Supp. 2d at 612 (holding “the Supreme Court in *eBay* did not state that loss of the right to exclude could not be irreparable harm.”). Thus, in *Novozymes*, this Court held that “Novozymes has suffered irreparable harm because of

Genencor's infringement on Novozymes right to exclude others from practicing its patent." *Id.*; *see also Brooktrout, Inc. v. Eicon Networks Corp.*, 2007 WL 1730112, at *1 (E.D. Tex. June 14, 2007) (granting injunction after *eBay* where "[t]he parties to this case are competitors ... and this fact weighs heavily in the court's analysis."); *O2 Micro Int'l Ltd. v. Beyond Innovation Tech Co.*, 2007 WL 869576, at *2 (E.D. Tex. Mar. 21, 2007) (granting injunction after *eBay* where "Micro competes directly with BiTEK, and this fact weighs heavily in the Court's analysis."); *Visto Corp. v. Seven Networks, Inc.*, 2006 WL 3741891, at *4 (E.D. Tex. Dec. 19, 2006) (granting injunction after *eBay* where "[t]he parties to this case are direct competitors, and this fact weighs heavily in the court's analysis" finding irreparable harm).

As in *Novozyms*, ACS is suffering irreparable harm because of Medtronic's infringement on ACS's right to exclude others from practicing the Lau patents. *See Novozyms*, 474 F. Supp. 2d at 612. Due to Medtronic's infringement, as a practical matter, rather than receiving a full patent term with the right to exclude others, ACS only enjoyed the exclusivity provided by the patents for a matter of months after the launch of ACS's revolutionary Multi-Link stent. *See* page 5, *supra*. As explained above, shortly after ACS released its patented Multi-Link stent, Medtronic began dumping massive numbers of infringing stents into the market. *See id.* And, based on its infringing use of ACS's patented technology, Medtronic took market share and position away from ACS. *See id.* Given that ACS and Medtronic are head-to-head competitors, Medtronic's infringement establishes irreparable harm. *See Visto*, 2006 WL 3741891, at *4 (granting injunction after *eBay* because "[i]ntellectual property enjoys its highest value when it is asserted against a direct competitor in the plaintiff's market.").

2. Medtronic's Infringement Has Taken Market Share from ACS and Damaged the Goodwill and Reputation of ACS's Stent Business

"[W]here a company pioneers an invention in the marketplace, irreparable harm flows from a competitor's attempts to usurp the pioneering company's market position and goodwill." *800 Adept, Inc. v. Murex Securities, Ltd.*, 2007 WL 1101238, at *6 (M.D. Fla Apr. 12, 2007) (granting injunction after *eBay*). Moreover, when an infringer takes market share away from a patent owner, the "patent owner's right to exclude 'cannot be compensated through monetary damages.'" *Black & Decker Inc. v. Robert Bosch Tool Corp.*, 2006 WL 3446144, at *4 (N.D. Ill. Nov. 29, 2006) (granting injunction after *eBay*); *see also id.* ("Loss of market share is a key consideration in determining whether a plaintiff has suffered irreparable harm."); *Smith & Nephew, Inc. v. Synthes (U.S.A.)*, 466 F. Supp. 2d 978, 983 (W.D. Tenn. 2006) (granting injunction after *eBay* because "[t]he loss of market share and the resulting lost profits and loss of brand name recognition which Smith & Nephew suffered because of Synthes' continued sale of the infringing products constitute injuries that are both incalculable and irreparable.").

As explained above, ACS's invention revolutionized the stent market by permitting physicians to treat tortuous vessels that could not be treated with stents in the past. *See* page 4, *supra*. Within three months after the release of the patented Multi-Link design, ACS acquired the leadership position with 64% market share. *See id.* But after only a few months of ACS's exclusivity, Medtronic began selling infringing products and taking ACS's market share. *See* page 5, *supra*. Medtronic's theft of ACS's market share for the past decade has caused irreparable harm to ACS. *Smith & Nephew*, 466 F. Supp. 2d at 985 (enjoining medical device product based on loss of market share and resulting lost profits and brand name recognition). Indeed, this irreparable harm continues to this very day, and Medtronic will not stop infringing ACS's patents unless and until the Court enjoins it. Where, as here, "the threat of continued

infringement exists, an injunction is appropriate.” *MGM Well Services, Inc. v. Mega Lift Sys., LLC*, 2007 WL 1231682, at *14 (S.D. Tex. Apr. 25, 2007) (granting injunction after *eBay*).

Furthermore, as explained above, Medtronic’s infringement damaged ACS well beyond lost sales.

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see also

Sanofi-Synthelabo v. Apotex Inc., 2007 WL 1746134, at *42 (S.D.N.Y. June 19, 2007) (granting injunction after *eBay* where infringement had “a negative impact on the amount of research devoted to developing other medical uses for Plavix®.”).

REDACTED

By diminishing ACS’s market share, Medtronic also irreparably damaged the value of ACS business as measured by its goodwill. *See* page 9, *supra*.

3. Medtronic’s Release of a Coated Version of Its Infringing Driver Stent Would Cause Further Irreparable Harm to ACS

As explained above, Medtronic intends to multiply its infringement by releasing a drug-coated version of its infringing Driver stent. *See* page 11, *supra*. Unless the Court enjoins Medtronic from infringing ACS’s patents, Medtronic likely will release its drug-coated Driver stent in the U.S. before the end of 2007. *See id.*

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If

Medtronic is the next entrant into the DES market, when ACS ultimately releases its own DES product, ACS likely will gain much less market share than it otherwise would have if Medtronic were not already on the market with an infringing DES product. (Ex. 6, Pacitti Decl. at ¶¶ 14-15.)

While ACS certainly welcomes fair competition, which already exists in the marketplace as a result of licenses to Boston Scientific and Cordis under the Lau patents, it would be unfair for Medtronic to beat ACS in the crucial race to the DES market with a stent that has already been found to infringe.

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Under such

circumstances, it likely would be difficult for ACS to regain a significant portion of the market share taken by Medtronic after ACS releases its own DES product. (*Id.* at ¶ 14.) But if Medtronic does not release a DES product into the U.S. market, ACS forecasts that its own DES product will gain a significant portion of the market share that would otherwise be taken by Medtronic. (*Id.* at ¶ 15.) Without question, therefore, Medtronic's release of its DES product into the U.S. stent market would damage ACS's market share, causing significant additional irreparable harm to ACS. This likelihood of future loss of market share based on Medtronic's continued infringement shows additional irreparable harm. *MGM Well*, 2007 WL 1231682, at *14 ("Because the threat of continued infringement exists, an injunction is appropriate.").

4. Irreparable Harm Should Be Presumed

In any event, under well-settled Federal Circuit law, "when a clear showing has been made of patent validity and infringement," irreparable harm is presumed. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1247 (Fed. Cir. 1989); *see also Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1381 (Fed. Cir. 2005). "This presumption derives in part from the finite term of the patent grant, for patent expiration is not suspended during litigation, and the passage of time can work irremediable harm." *H.H. Robertson Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 390 (Fed. Cir. 1987), *overruled on other grounds*, *Markman v. Westview Instr., Inc.*, 52 F.3d 967 (Fed. Cir. 1995). This reasoning applies acutely here, since Medtronic has been infringing ACS's patents for nearly a decade, and they expire in just a few years.

The presumption of irreparable harm was not abrogated by *eBay*. While *eBay* held that a patentee is not automatically entitled to an injunction upon a finding of infringement, mandating that district courts exercise their discretion in a manner “consistent with traditional principles of equity,” 126 S.Ct. at 1841, it did not address or modify the presumption of irreparable harm that applies after a patent has been found to be valid and infringed. There is no reason this Court should decline to issue an injunction where, as here, the evidence and the verdict show that Medtronic has been infringing ACS’s patents for nearly a decade. *See e.g., Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006) (discussing the presumption of irreparable harm after *eBay*, and finding that the plaintiff requesting a preliminary injunction was not entitled to the presumption only because it had not established a likelihood of success on the merits); *Christiana Indus. Inc. v. Empire Electronics, Inc.*, 443 F. Supp. 2d 870, 884 (E.D. Mich. 2006) (“Plaintiff argues, and this Court agrees, that *Ebay* did not invalidate the presumption.”).⁹

Here, patent infringement and validity have been proven. A jury has found that all twelve of Medtronic’s accused stents infringe multiple claims of multiple ACS patents, and that none of the asserted claims is invalid. And the Court has denied Medtronic’s post-trial motions and entered judgment that the patents are all valid, enforceable, and infringed. Thus, irreparable harm should be presumed. *See Richardson*, 868 F.2d at 1247.

⁹ While ACS respectfully submits that the presumption remains intact after *eBay* in light of *Abbott Labs.* and the other Federal Circuit cases cited above, ACS notes that this Court has characterized the presumption as “now-overturned,” *IMX, Inc. v. Lendingtree, LLC*, 469 F. Supp. 2d 203 (D. Del. 2007), and that several other district courts have declined to apply the presumption after *eBay*. *See Voda v. Cordis Corp.*, 2006 WL 2570614 (W.D. Okla. Sept. 5, 2006); *Paice LLC v. Toyota Motor Corp.*, 2006 WL 2385139 (E.D. Tex. Aug. 16, 2006); *z4 Techs., Inc. v. Microsoft Corp.*, 434 F. Supp. 2d 437 (E.D. Tex. 2006). In any event, ACS has established irreparable harm, regardless of whether the presumption applies. *See* pages 14-19, *supra*.

B. Remedies at Law Will Not Adequately Compensate ACS

For reasons similar to those demonstrating irreparable harm,¹⁰ monetary damages will not make ACS whole for Medtronic's infringement. As Chief Justice Roberts explained:

From at least the early 19th century, courts have granted injunctive relief upon a finding of infringement in the vast majority of patent cases. This “long tradition of equity practice” is not surprising, given the difficulty of protecting a right to *exclude* through monetary remedies that allow an infringer to *use* an invention against the patentee's wishes — a difficulty that often implicates the first two factors of the traditional four-factor test.

eBay, 126 S. Ct. at 1841 (Roberts, C.J., concurring) (emphasis in original); *see also Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1456-57 (Fed. Cir. 1988) (“It is well-settled that, because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole.”); *Reebok Int'l, Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1557 (Fed. Cir. 1994) (“Because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole.”). As stated by this Court, “there are certain tangential benefits associated with patent rights, such as a marketplace reputation for enforcing one's patents, the value of which cannot be quantified in monetary damages.” *Fisher-Price, Inc. v. Safety 1st, Inc.*, 279 F. Supp. 2d 526, 528 (D. Del. 2003).

The harm caused by Medtronic's continuing infringement cannot be adequately remedied by monetary damages. Where the patentee and infringer are head-to-head competitors, such as

¹⁰ “[A]s noted by the Court of Appeals for the Fifth Circuit, ‘[o]ften times the concepts of “irreparable injury” and “no adequate remedy at law” are indistinguishable’ in the context of a permanent injunction.” *800 Adept*, 2007 WL 1101238, at *6 (citing *Lewis v. S.S. Baune*, 534 F.2d 1115, 1124 (5th Cir. 1976)).

ACS and Medtronic, and the infringer has taken the patentee's market share, this Court has held that "the statutory right to exclude represents a benefit that ... cannot be equated by an award of cash." *Novozymes*, 474 F. Supp. 2d at 613.

Moreover, "where the infringing device will continue to infringe and thus damage Plaintiffs in the future, monetary damages are generally considered to be inadequate." *3M Innovative Props. Co. v. Avery Dennison Corp.*, 2006 WL 2735499, at *1 (D. Minn. Sept. 25, 2006) (citation omitted). In this case, Medtronic will continue to infringe into the future and, indeed, intends to multiply its infringement significantly by selling its infringing Driver stent as part of its DES product. *See* page 11, *supra*. As explained above, due to negative press affecting the Cypher and Taxus stents, the next entrant into the DES segment of the stent market will have the opportunity to take market share from Cordis and Boston Scientific, and to cement long-standing relationships with customers. *See* page 12, *supra*. If Medtronic is permitted to enter the DES market with a product based on its infringing Driver stent, ACS will be damaged in ways that cannot be adequately compensated with money. *Smith & Nephew*, 466 F. Supp. 2d at 984 ("Monetary damages generally are not an adequate remedy against future infringement because the central value of holding a patent is the right to exclude others from using the patented product.").

Additionally, a remedy at law would be insufficient because it would not adequately compensate ACS for other damages that Medtronic's future infringement would cause. Aside from losing sales, Medtronic's entrance into the DES market would: (1) damage the goodwill of ACS's business;

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See pages 8-9, *supra*; (Ex. 6, Pacitti Decl. at ¶ 16). These types of harms are not

easily quantifiable and thus not fully compensable by money damages. *Smith & Nephew*, 466 F. Supp. 2d at 984 (holding “intangible losses, such as the loss of goodwill, can never be ascertained accurately” and thus cannot be adequately compensated by monetary damages).

While ACS cross-licensed its Lau patents to Cordis and Boston Scientific to settle litigation, ACS’s decision to grant licenses under these limited circumstances does not show that monetary damages would adequately remedy Medtronic’s infringement. ACS has a general policy against licensing its Lau patents for money alone, and has no interest in licensing them to Medtronic. *See* pages 9-10, *supra*; *MGM Well*, 2007 WL 1231682, at *14 (“Because MGM is not willing to license Mega Lift to practice the 060 Patent, MGM would likely be required to engage in protracted and repeated litigation against Mega Lift if there is no permanent injunction”); *3M Innovative*, 2006 WL 2735499, at *1 (“The Court will not disturb [a patentee’s] determination that its business interests will not be served by the licensing of this product.”). ACS’s unwillingness to license its Lau patents to third parties outside a significant settlement, cross-license, or joint development context shows that money alone cannot compensate for Medtronic’s infringement.¹¹

C. The Balance of Hardships Favors ACS

The balance of hardships favors ACS. As explained above, ACS has been suffering irreparable harm to its stent business ever since Medtronic released its first infringing product nearly a decade ago. In contrast, by helping itself to ACS’s patented technology, Medtronic has

¹¹ In any event, the Supreme Court expressly rejected the notion that a “plaintiff’s willingness to license its patents” . . . would be sufficient to establish that the patent holder would not suffer irreparable harm if an injunction did not issue.” *eBay*, 126 S. Ct. at 1840-41; *see also Commonwealth Scientific and Industrial Research Organisation v. Buffalo Tech. Inc.*, 2007 WL 1739999, at *5 (E.D. Tex. June 15, 2007) (granting injunction after *eBay* even where patentee did not sell patented products and licensed its patent to third parties).

been taking market share from ACS and has damaged its goodwill and reputation in the market place. *See* pages 6-9, *supra*. And, based on sales of its infringing stents, Medtronic continues to take market share away from ACS to this day. *See* page 7, *supra*. In the foreseeable future, moreover, Medtronic intends to exacerbate its infringement by selling even more of its infringing Driver stents as part of its DES products. *See* page 11, *supra*. This future harm weighs in favor of an injunction. *Black & Decker*, 2006 WL 3446144, at *5 (holding “the balance of hardship factors tips in favor of Black & Decker because the harm caused by future infringement by the [infringing products] outweighs any hardship that [the defendant] may experience.”); *Brooktrout*, 2007 WL 1730112, at *2 (the “right to exclude ... is the essence of the intellectual property at issue.”).

On the other hand, while Medtronic would lose some revenue from an injunction, Medtronic’s U.S. sales¹² of infringing stents accounted for only 0.21% of its \$11.3 billion in 2006 sales. *See* page 11, *supra*. Given that Medtronic’s sales of infringing stents are a negligible fraction of its total revenue, Medtronic will not suffer any unreasonable hardship from an injunction and by no means will be driven out of business. *See Smith & Nephew*, 466 F. Supp. 2d at 984 (“Mere hardship incurred in the process of ceasing operations, however, is not sufficient.”).

Moreover, while ACS does not dispute that Medtronic’s plans to release a drug-coated version of the infringing Driver stent in the U.S. will be hurt by an injunction, any such harm was entirely foreseeable and the direct result of Medtronic’s decisions to sell only infringing stents. Medtronic has been on notice of its infringement for nearly ten years, and has known

¹² To the extent that Medtronic is making infringing stents in the U.S. for sale abroad, such stents would also be infringing and subject to an injunction.

about the jury verdict for the past two and a half years. During that entire time, Medtronic could have pursued noninfringing alternatives to ACS's patented design, but chose not to, at its own risk. *See MGM Well*, 2007 WL 1231682, at *15 (holding defendant "is free to focus on the sale of these non-infringing systems and an injunction against selling infringing systems should not impose an unreasonable hardship."). Instead, Medtronic continued to infringe ACS's Lau patents as if it had a license to do so.

To the extent Medtronic invested capital in developing or marketing any additional infringing products, it knowingly assumed that risk. For example, although Medtronic is using its infringing Driver stent as a platform for its DES product, it should not be heard to complain about any lost investments that may result from an injunction because it has known that the Driver infringed for many years now.¹³ Medtronic is free to release a DES product that uses a noninfringing stent platform, such as Medtronic's Wiktor or Boneau stents, but it should not be permitted to continue using ACS's patented, connected-ring design. *See Windsurfing*, 782 F.2d at 1003 n.12 ("One who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected.").

D. The Public Interest Favors Issuance of a Permanent Injunction

1. Public Policy Favors Enforcement of Patent Rights

As explained by the Federal Circuit, the public interest is best served by enforcing patents, such as ACS's Lau patents, that are valid and infringed. *Abbott Labs*, 452 F.3d at 1348;

¹³ Of course, Medtronic could not reasonably claim that it has lost any significant investment in its DES product if an injunction issues in the U.S., given that Medtronic markets its DES product outside of the U.S. Indeed, according to its 2006 Annual Report, Medtronic's sales of its DES product outside of the U.S. last year amounted to \$138 million. (Ex. 17 at 26.) If those stents were not manufactured in whole or in part in the United States, they would not infringe the patents-at-issue and would not be subject to the proposed injunction.

see also 800 Adept, 2007 WL 1101238, at *8 (“The public has an interest in maintaining a strong patent system.”) (citation omitted). Moreover, in this case, the issuance of a “permanent injunction will further consumer access to more competitive, and thus, presumably better, products by allowing [the patentee] the benefit of its patents and the ability to gain greater brand recognition.” *Smith & Nephew*, 466 F. Supp. 2d at 985 (enjoining infringing medical device). By the same token, “without the right to obtain an injunction, the right to exclude granted to the patentee would have only a fraction of the value it was intended to have, and would no longer be as great an incentive to engage in the toils of scientific and technological research.” *Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 397 F. Supp. 2d 537, 547 (D. Del. 2005) (citation omitted).

In this case, ACS devoted millions of dollars and countless hours of research to developing the technology described in the Lau patents. (D.I. 636 at 1459.) As a result of ACS’s invention, for many patients, coronary artery disease can be treated by placement of a stent—even in the most tortuous of vessels—to avoid the significant risks of open-heart surgery. (D.I. 631 at 245-252.). After disclosing this technology to the public in its Lau patents, ACS should be rewarded with its hard-earned right to exclude others. Accordingly, the public interest favors granting an injunction.

2. The Public Would Have Access to Sufficient Stents Without Medtronic’s Infringing Products on the Market

Furthermore, given the volume of non-infringing, competing products available in the marketplace from both ACS and its licensees, the public will have access to sufficient stents even without Medtronic’s infringing products on the market. *See Smith & Nephew*, 466 F. Supp. 2d 978 (“No considerable hardship will be imposed on physicians or patients when the injunction is imposed because other competing products would fill any temporary void created by the

injunction.”) As explained above, ACS has the capacity to supply all of the stents Medtronic currently sells in the United States. *See* page 12, *supra*. Moreover, ACS, Cordis, and Boston Scientific already supply competing stents that can be used in place of Medtronic’s infringing products. *See* page 13, *supra*.

Finally, Medtronic itself has clearly manifested the opinion that injunctions are appropriate in stent cases, for it asked for an injunction in *this very case*, on the Boneau patents. And Medtronic also apparently believes that injunctions are equally appropriate on drug-eluting stents, for it is currently seeking injunctions in other cases against ACS’s, Boston Scientific’s, and Cordis’s DES and metal stent products. (Ex. 22 at 6; Ex. 19 at 6.) Thus, Medtronic has no room to argue that injunctions on stents (including DES) are contrary to the public interest.

E. The Scope of the Injunctive Relief Sought by ACS Is Appropriate

An appropriate injunction is one which “prevent[s] the violation of any right secured by patent, on such terms as the court deems reasonable.” 35 U.S.C. § 283. ACS’s proposed Permanent Injunction Order (“Order”) (filed herewith) satisfies both § 283 and Federal Rule of Civil Procedure 65(d), which governs the form of injunctions.

ACS’s proposed Order is narrowly tailored to protect ACS’s patent rights. Specifically, the provisions of the Order are narrowly crafted to enjoin only products litigated, products not colorably different therefrom, and products that contain or use the infringing stents. *See KSM Fastening Sys., Inc. v. H.A. Jones Co.*, 776 F.2d 1522, 1526 (Fed. Cir. 1985) (“contempt proceedings, civil or criminal, are available only with respect to devices previously admitted or adjudged to infringe, and to other devices which are no more than colorably different therefrom and which clearly are infringements of the patent”). The proposed Order tracks the language of 35 U.S.C. § 271 and Fed. R. Civ. P. 65(d) to specifically list the acts of infringement from which

Medtronic will be enjoined. Thus, the Court can and should enter an injunction in the form of the proposed Order

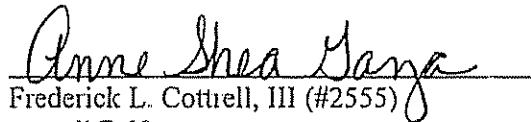
VI. CONCLUSION

For the reasons stated above, the Court should permanently enjoin Medtronic from making, using, selling, offering to sell, or importing devices that have been found to infringe the Lau patents, including the Microstent II, GFX, GFX 2, GFX 2.5, S540, S660, S670, S7, BeStent 2, Driver, MicroDriver, Racer, any devices no more than colorably different from these infringing devices, and any products containing or using any of these infringing stents

Of Counsel:

J. Michael Jakes
Gerald F. Ivey
Michael A. Morin
FINNEGAN, HENDERSON, FARABOW
GARRETT & DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001-4413
(202) 408-4000

Dated: June 29, 2007


Frederick L. Cottrell, III (#2555)

cottrell@rlf.com

Anne Shea Gaza (#4093)

gaza@rlf.com

RICHARD, LAYTON & FINGER

One Rodney Square

P.O. Box 551

Wilmington, Delaware 19899

(302) 651-7509

*Attorneys for Plaintiffs Abbott Cardiovascular
Systems Inc. and Abbott Laboratories Inc.*

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

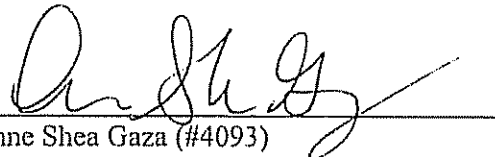
I hereby certify that on June 29, 2007, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

Karen Jacobs Loudon, Esquire
Morris, Nichols, Arshl & Tunnell
1201 N. Market Street
P O. Box 1347
Wilmington, Delaware 19899-1347

I hereby certify that on June 29, 2007, I have sent by Federal Express the foregoing document to the following non-registered participants:

Raphael V. Lupo, Esquire
Donna M. Tanguay, Esquire
Mark G. Davis, Esquire
McDermott, Will & Emery
600 13th Street, N.W.
Washington, DC 20005

George M. Sirilla, Esquire
William P. Atkins, Esquire
Pillsbury Winthrop Shaw Pittman LLP
1650 Tysons Boulevard
14th Floor
McLean, VA 22102-4859



Anne Shea Gaza (#4093)
Richards, Layton & Finger, P.A.
One Rodney Square
P.O. Box 551
Wilmington, Delaware 19899
(302) 651-7700
gaza@rlf.com

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on July 9, 2007, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

Karen Jacobs Loudon, Esquire
Morris, Nichols, Arsht & Tunnell
1201 N. Market Street
P.O. Box 1347
Wilmington, Delaware 19899-1347

I hereby certify that on July 9, 2007, I have sent by Federal Express the foregoing document to the following non-registered participants:

Raphael V. Lupo, Esquire
Donna M. Tanguay, Esquire
Mark G. Davis, Esquire
McDermott, Will & Emery
600 13th Street, N.W.
Washington, DC 20005

George M. Sirilla, Esquire
William P. Atkins, Esquire
Pillsbury Winthrop Shaw Pittman LLP
1650 Tysons Boulevard
14th Floor
McLean, VA 22102-4859


Anne Shea Gaza (#4093)
Richards, Layton & Finger, P.A.
One Rodney Square
P.O. Box 551
Wilmington, Delaware 19899
(302) 651-7700
gaza@rlf.com